US009114366B2

(12) **United States Patent**
Hunt et al.

(10) **Patent No.: US 9,114,366 B2**
(45) **Date of Patent: *Aug. 25, 2015**

(54) **DISPOSABLE TANGENTIAL FLOW FILTRATION DEVICE HOLDER**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/446,103**

(22) Filed: **Apr. 13, 2012**

(65) **Prior Publication Data**

US 2012/0192958 A1 Aug. 2, 2012

Related U.S. Application Data

(63) Continuation of application No. 11/404,287, filed on Apr. 14, 2006, now Pat. No. 8,177,974.

(51) **Int. Cl.**

B01D 25/00	(2006.01)
B01D 29/01	(2006.01)
B01D 61/18	(2006.01)
B01D 61/20	(2006.01)
B01D 63/08	(2006.01)

(52) **U.S. Cl.**

CPC ***B01D 61/18*** (2013.01); ***B01D 61/20*** (2013.01); ***B01D 63/082*** (2013.01); ***B01D 63/087*** (2013.01); *B01D 2313/04* (2013.01); *B01D 2313/08* (2013.01); *B01D 2313/10* (2013.01); *Y10T 137/0402* (2015.04)

(58) **Field of Classification Search**

USPC 210/321.6, 321.75, 321.84, 224–229, 210/231, 450, 455

See application file for complete search history.

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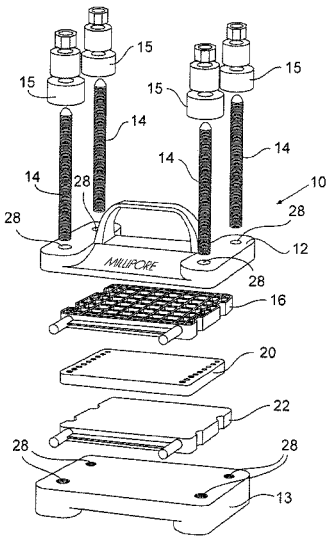
(57) **ABSTRACT**

Tangential flow filtration device is provided wherein liners are provided between the filtration element and the top and bottom holders or manifolds. The liners incorporate the flow channels and inlet and outlet ports that were previously present in the manifolds. The liners are made of an inexpensive material and therefore are disposable after a single use, making it more cost effective to dispose of them than to clean the conventional manifolds. In addition, the liners can be pre-sterilized.

5 Claims, 3 Drawing Sheets



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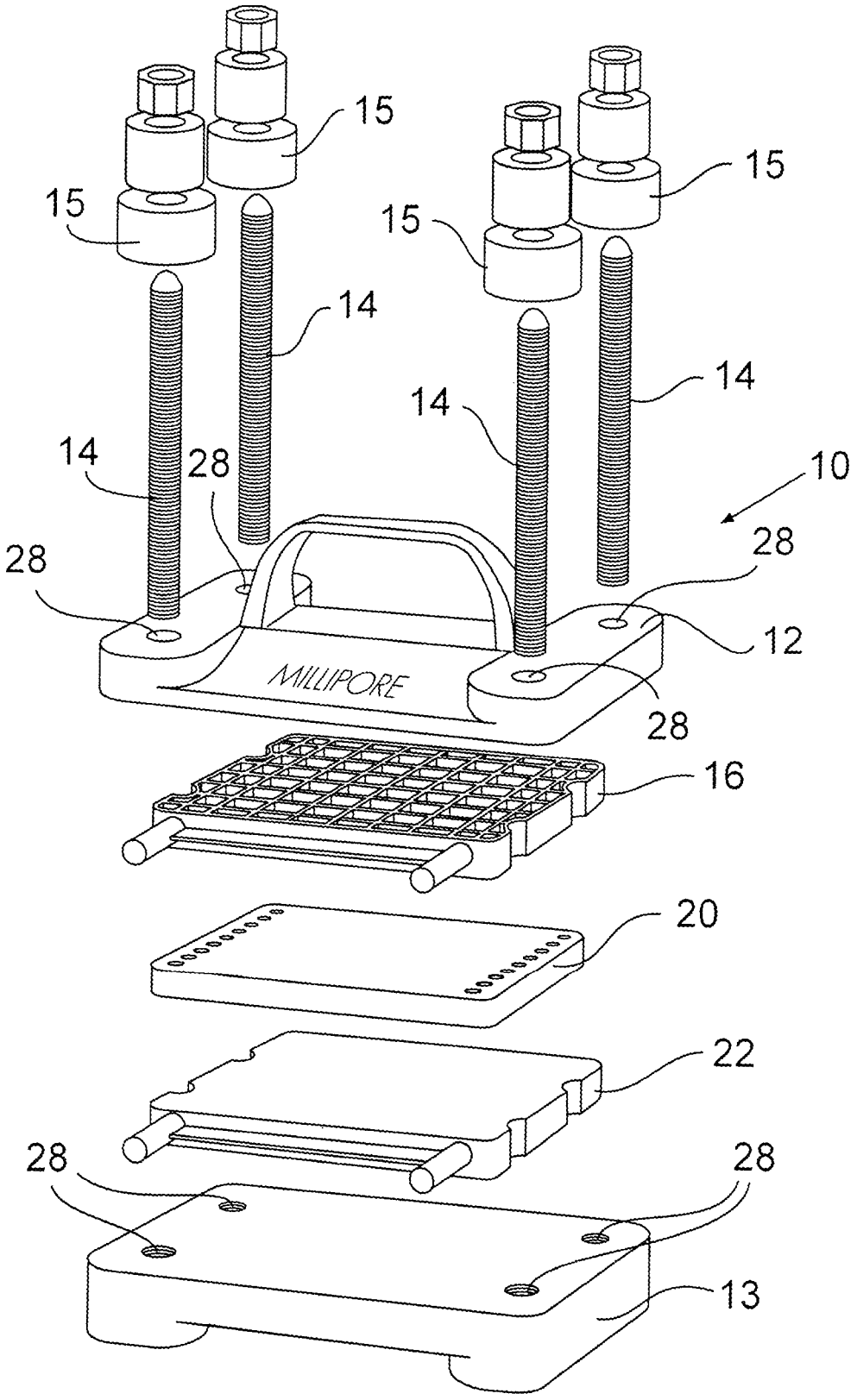

Figure 1

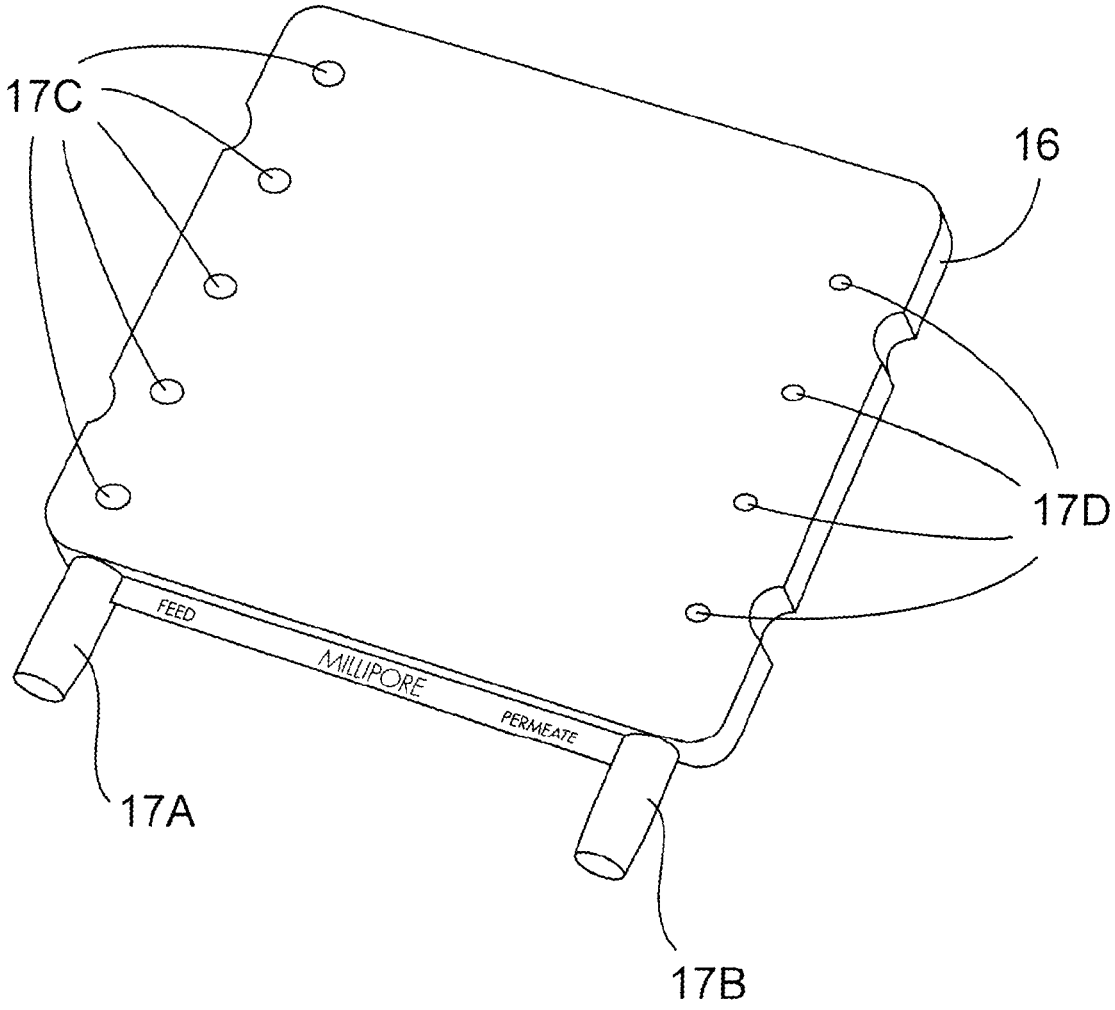

Figure 2

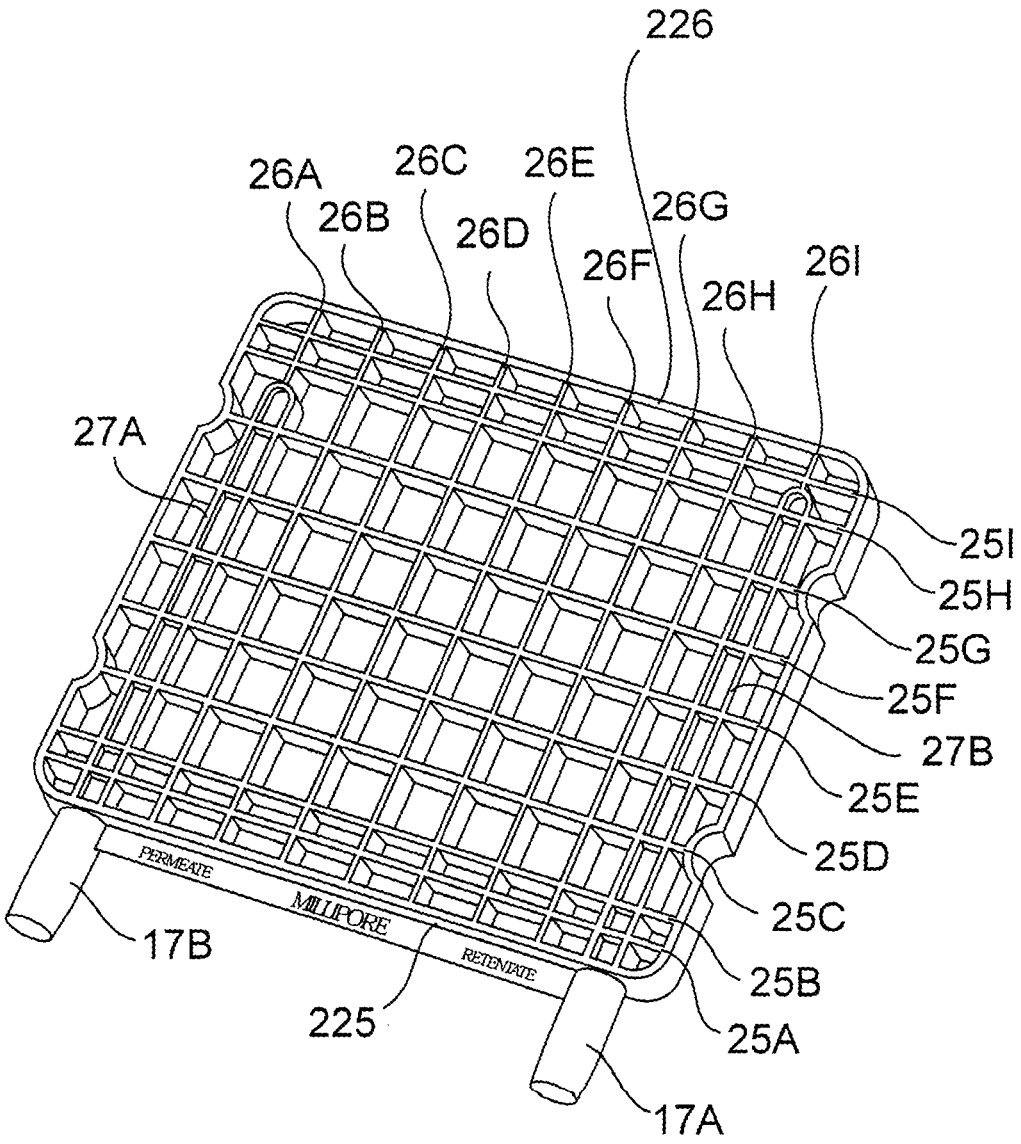
226
26A
26B
26C
26D
26E
26F
26G
26H
26I
27A
25I
25H
25G
25F
27B
25E
25D
25C
25B
25A
17A
17B
225
PERMEATE
MILLIPORE
RETENTATE

Figure 3

DISPOSABLE TANGENTIAL FLOW FILTRATION DEVICE HOLDER

This application is a continuation of U.S. patent application Ser. No. 11/404,287 filed Apr. 14, 2006, the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Tangential Flow Filtration (TFF) is a separation process that uses membranes to separate components in a liquid solution or suspension on the basis of size or molecule weight differences. Applications include concentration, clarification, and desalting of proteins and other biomolecules such as nucleotides, antigens, and monoclonal antibodies; buffer exchange; process development; membrane selection studies; pre-chromatographic clarification to remove colloidal particles; depyrogenation of small molecules such as dextrose and antibiotics; harvesting, washing or clarification of cell cultures, lysates, colloidal suspensions and viral cultures; and sample preparation.

In TFF, the solution or suspension to be filtered is passed across the surface of the membrane in a cross-flow mode. The driving force for filtration is the transmembrane pressure, usually created with a peristaltic pump. The velocity at which the filtrate is passed across the membrane surface also controls the filtration rate and helps prevent clogging of the membrane. Because TFF recirculates retentate across the membrane surface, membrane fouling is minimized, a high filtration rate is maintained, and product recovery is enhanced.

Conventional TFF devices are formed of a plurality of elements, including a pump, a feed solution reservoir, a filtration module and conduits for connecting these elements. In use, the feed solution is directed from the feed solution reservoir to the filtration module while the retentate from the filtration module is recirculated from the filtration module to the feed solution reservoir until the desired volume of retentate is obtained. The membrane is sandwiched between top and bottom manifolds or holders, which serve to provide accurate mechanical constraint against the internal hydraulic pressure of the device, and also serve to distribute the filtration stream across the multiple flow paths within the device. These manifolds or holders are typically made of stainless steel and must be cleaned and validated prior to each use, particularly in biopharmaceutical and other sanitary applications. This is an expensive and time-consuming process.

It would be desirable to provide a filtration device that eliminates the need for the aforementioned cleaning and validation steps when replacing the filtration medium.

SUMMARY OF THE INVENTION

In accordance with the present teachings, a tangential flow filtration device is provided wherein liners are provided between the filtration element and the top and bottom holders or manifolds. The liners incorporate the flow channels and inlet and outlet ports that were previously present in the manifolds. The liners are made of an inexpensive material and therefore are disposable after a single use, making it more cost effective to dispose of them than to clean the conventional manifolds. In addition, the liners can be pre-sterilized. In order to provide sufficient strength and rigidity under operating conditions, the liners have a grid pattern of ribs that abut the holder plates to help prevent the liners from torquing under clamping force.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded view of the filtration device in accordance with the present invention;

FIG. **2** is a top perspective view of a liner in accordance with the present invention; and

FIG. **3** is bottom perspective view of a liner in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Turning first to FIG. **1**, there is shown an exploded view of a filtration device **10** in accordance with the instant teachings. The device **10** includes a top holder plate **12** and a spaced bottom holder plate **13**. The holder plates **12**, **13** are preferably made of stainless steel and are sufficiently rigid and durable to provide accurate and effective mechanical constraint of the assembly against internal hydraulic operating pressures, such as 50-60 psi. Apertures **28** are provided in the holder plates **12**, **13** and in each layer of the assembly to accommodate tie rods or threaded pins or bolts **14** or other clamping device to secure the assembly together. Spacers **15** are provided, and can be spring-loaded. No filtration stream passageways are present in the holder plates **12**, **13**.

Positioned beneath holder plate **12** in the assembled state is disposable liner **16**. The liner **16** is preferably made of inexpensive material, suitable for the application, that is acceptable for pharmaceutical assays (and preferably is government approved). Suitable materials of construction include plastics, such as polystyrene, preferably polyolefins, such as polypropylene, polyethylene, copolymers and mixtures thereof. Polysulfone is particularly preferred in view of its strength and rigidity. The liner **16** is preferably molded with passageways and openings. Alternatively, and less preferred, it may be formed by milling, drilling and other such methods.

As best seen in FIG. **2**, the liner **16** includes a first port **17**A, five sub-ports **17**C a second port **17**B and four sub-ports **17**D. Port **17**A is for introduction of feed or removal of retentate depending on its orientation within the assembly, with port **17**B for removal of permeate, while preventing admixture of the filtrate with the retentate or feed, as is conventional. Port **17**A is connected to the five sub-ports **17**C in a manifold arrangement. Port **17**B is connected to the four sub-ports **17**D in a similar manner. The ports **17**A and **17**B may be located on opposite sides of the liner in order to provide adequate spacing and avoid interferences with other components. However, in the application shown, where spacing is sufficient or no interference occurs, they may be located on the same side. Each port **17**A, **17**B is in fluid communication with flow paths or passageways that communicate with respective apertures to accommodate flow of feed, retentate or permeate as is conventional, thereby defining multiple flow paths for the filtration stream within the device.

The passageways are preferably tapered, narrowing as they proceed away from their respective port, to normalize pressure at each of the sub-ports **17**C and **17**D.

Turning back to FIG. **1**, there is shown positioned below liner **16** a filtration element **20**. The filtration element **20** can be a single membrane, and is preferably a plurality of stacked membranes, such as stacked ultrafiltration or microfiltration membranes, most preferably provided in the form of a cassette. Although a single cassette of membranes is shown, those skilled in the art will appreciate that multiple cassettes can be used. Suitable cassettes are sold under the name PELLICON® and are commercially available from Millipore Corporation.

Positioned below the filter element **20** is a second liner **22**. Preferably the second liner **22** is identical in construction to the first liner **16**, but is when the device is in the assembled state, the liner **22** is inverted relative to the position of the first liner **16**, as shown. This allows Port **17**A to communicate with the feed ports of the device in its normal orientation, while communicating with the retentate ports while in the inverted position. Port **17**B of the liner communicates with the permeate ports in both orientations.

Preferably one side of the liners **16**, **20** includes a plurality of inter-engaging ribs, as best seen in FIG. **3**. The ribs provide added rigidity to the liners, and can be formed in the molding process. The ribs are positioned on the side of the liner that contacts the holder plate. The ribs extend from one side of the liner to the other, except where interrupted by a port. In the rib configuration shown, a grid is formed by a plurality of longitudinal and latitudinal ribs, with nine latitudinal ribs **25**A-**25**I and nine longitudinal ribs **25**A-**26**I. The latitudinal ribs are preferably parallel with one another, and the longitudinal ribs are preferably parallel with one another and perpendicular to the latitudinal ribs. The latitudinal ribs **25**B-**25**H are preferably equally spaced, whereas the respective spaces between latitudinal rib **25**A and **25**B and **25**A and the sidewall **225** of the liner are smaller, as are the spaces between ribs **25**H and **25**I and rib **25**I and the opposite sidewall **226** of the liner. Clustering the ribs more closely together at the sidewalls provides additional strength to the liner. Longitudinal ribs **25**A-**26**I are all equally spaced, with the spacing preferably the same or substantially the same as that of latitudinal ribs **25**B-**25**H, so that the grid defined between ribs **25**B-**25**H and ribs **26**A-**26**I includes a plurality of squares, the grid formed between ribs **25**H, sidewall **226**, and ribs **26**A-**26**I includes a plurality of rectangles, and the grid formed between ribs **25**B and sidewall **225** and ribs **26**A-**26**I includes a plurality of rectangles. A U-shaped rib **27**A is formed around the permeate port **17**B, as is U-shaped rib **27**B around retentate port **17**A.

The intricate rib configuration shown provides strength and rigidity to the liner. When assembled, there is significant clamping force applied to the filter element and the liner, with sealing taking place between the smooth side of the liner and the filter element **20**. Without the rib configuration, the liner would not remain flat, and therefore would not seal properly to the filter element **20**. The ribs make it possible to effectively assemble the liners in the filtration device of the invention, in sealing engagement upon the application of pressure, without the necessity of having corresponding grooves in the holder plates to mate with the ribs. Accordingly, the respective surfaces of the holder plates that abut the grids of the liners are preferably flat, and need not be specially designed to fit the liners.

What is claimed is:

1. A method of assembling a filtration apparatus, comprising:

providing a top plate devoid of a fluid flow path and having a grooveless substantially flat surface; a bottom plate devoid of a fluid flow path and having a grooveless substantially flat surface; a filtration member; a first disposable liner having a fluid inlet, a fluid outlet, a plurality of fluid inlet apertures, and a pattern of ribs on one side thereof; a second disposable liner having a fluid inlet, a fluid outlet, a plurality of fluid outlet apertures and a pattern of ribs on one side thereof;

bringing together said top plate, said first and second liners, said filtration member and said bottom plate such that said substantially flat surface of said top plate abuts against said pattern of ribs on said first disposable liner and said substantially flat surface of said bottom plate abuts against said pattern of ribs on said second disposable liner, and said filtration member is positioned between said first and second disposable liners, to form a filtration assembly; and

applying a clamping force to said filtration assembly, causing said respective patterns of ribs on said first and second liners to seal against the respective said grooveless substantially flat surfaces of said top and bottom plates.

2. The method of claim **1**, wherein each said pattern of ribs defines a grid pattern, each said grid pattern retaining a respective liner in a flat configuration when mated with the respective top and bottom plates and subjected to pressure.

3. The method of claim **1**, wherein said plurality of ribs on each respective liner are inter-engaging.

4. The method of claim **1**, wherein said plurality of ribs on each of said first and second disposable liners comprises a plurality of parallel latitudinal ribs and a plurality of parallel longitudinal ribs perpendicular to said plurality of latitudinal ribs.

5. The method of claim **4**, wherein said plurality of longitudinal ribs are equally spaced.

* * * * *